

### Remarks

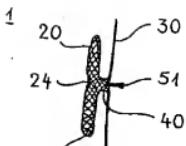
The Office Action mailed November 22, 2010 has been carefully considered. Reconsideration and allowance of the subject application, as amended, are respectfully requested.

Claims 40-50, 52-63 and 65-73 remain pending in the application.

As an initial matter, the drawings were objected to on the grounds that “the tissue and/or scrim and other net structure” in claim 40 and “the thickness and concentration of material is different across the implantable device from distal portion to proximate portion” in claim 48 are not shown in the drawings.

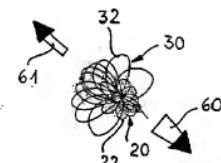
Claim 40 has been amended to recite “the support structure comprising a single intertwined, inter-coiled wire-like element having two ends and configured into a tissue and/or scrim and/or net structure. Support may be found at paragraph [0020] of the published U.S. application which recites “[d]epending on how the intermediate portion is configured, either a defined through-opening can then be generated through it, or a complete or partial occlusion of the opening in the wall. Preferably, by suitable coiling, intertwining and twisting, an elongate tube with a tissue, scrim or net structure is first formed from the just one wire-like element.” Paragraph [0018] recites “[t]he support structure is preferably formed by intercoiling and/or intertwining of the wire-like element in the manner of a tissue, scrim, braid, net or the like. Despite using only one wire-like element, such a support structure can be formed by coiling, interlacing or interweaving, the support structure having a tissue, scrim and/or net structure.”

In other words, the intercoiling and/or intertwining of the wire-like element forms a tissue, scrim or net structure (“in the manner of”). This is evident in FIGS. 1, 2-2d, 3-3a, 4-4a, 5, 7-7c, 8-8e, 11a-e, 12a, 17a-e and 19a-b. Accordingly, Applicant submits that the tissue, scrim or net structure is shown in the drawings as it is the structure (porous or open “weave”) formed by intercoiling and/or intertwining of the wire-like element. See, for instance, FIG. 7 below.

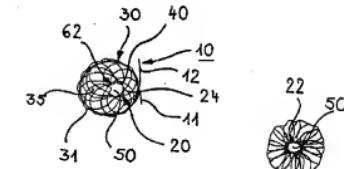


*Fig. 7*

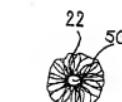
With regard to the claim 48 and support in the drawings that the thickness and concentration of material is different across the implantable device from distal portion to proximal portion, Applicant submits that **FIG. 5** illustrates a difference in concentration of coiled wire between the distal portion **30** (light) and the proximal portion **20** (heavy). **FIG. 5** shows a similar characteristic (**20** light, **30** heavy). See below and paragraph [0024] for support.



*Fig. 5*



*Fig. 6*



*Fig. 6d*

It is further submitted that **FIGS. 5 vs. 6a** show a thickness difference of material (loops **22**) between distal portion **30** and proximal portion **20**.

Claims 48 and 67 have been amended to correct grammatical errors. No new matter has been entered.

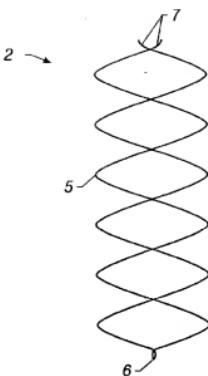
Claims 40-50, 52-63 and 65-75 have been rejected under 35 U.S.C. § 112, second paragraph, for being indefinite. Claim 40 has been amended as noted above to correct this rejection by reciting “a single intertwined, inter-coiled wire-like element having two ends and configured into a tissue and/or scrim and/or net structure”. In addition, claim 49 has been rejected for reciting “a single wire element having different diameters”. Claim 49 has been amended to recite “a single wire element having different diameters along different portions of its length”. No new matter has been entered.

Claims 40-50, 52-59, 63, 65 and 66 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Amplatz et al. (US 5,944,738) in view of newly cited Hyodoh et al. et al. (US 20033/0149475) and Shaw et al. (US 6,171,329).

Ampaltz appears to be directed at a collapsible medical device comprising a tubular metal fabric of woven metal *strands*. The Office Action admits at page 6 that Amplatz et al do not disclose that the support structure is formed from a single wire-like element and turns to newly cited Hyodoh et al. et al. This can also be clearly seen in **FIGS. 1-12** of Amplatz where the wires of the tubular braided metal fabric device are fixed by clamps **30, 32** at both ends.

Hyodoh et al. et al. discloses an implantable device comprising a single wire element (paragraphs [0146]-[0152] and [0233]; **FIGS. 1C, 50A, 50B, 50C, 57A-D**) where the wire is twisted or looped. The devices may be created by bending shape memory wires around tabs projecting from a template, and weaving the ends of the wires to create the body of the device *such that the wires cross each other to form a plurality of angles*, at least one of the angles being obtuse. In other words, Hyodoh et al. teaches an open structure (see below) and not configured into “a tissue and/or scrim and/or net structure”. Applicant submits that a complex structure such as the occluding device of the present application is not taught or suggested by Hyodoh et al.

Regarding the motivation to combine Amplatz and Hyodoh et al., Applicant submits that the braid structure of Amplatz requires at least three wire strands and that all (single wire) FIGS. according to Hyodoh et al. show only one wire loop with the two ends crossed and are absent a hollow braided structure.



**FIG. 1C**

The Examiner references **FIGS. 50A** and **57B-D** of Hyodoh et al. as a support structure formed from a single intertwined, intercoiled wire-like element. Applicant submits that the structure in those FIGS. is not intertwined or intercoiled “and configured into a tissue and/or scrim and/or net structure” as recited in amended claim 40. **FIG. 50A** has a structure much like **FIG. 1C** above, a series of helically twisted segments, while **FIGS. 57B-D** have a similar base structure but further include separate metal coil pieces **714** or fibers **716** in order to function as an occluding device (see paragraphs [0238]-[0241] of Hyodoh et al.). The present invention relies on the single wire being intercoiled or intertwined with itself to form a tissue and/or scrim and/or net structure which by itself acts as an occluding device.

Shaw et al. appears to be directed at a self-expanding device for sealing a defect in a wall, such as a septal defect. The device has a helical shaped wire periphery formed from an elastic wire and at least one eyelet. Further, Shaw et al. requires a membrane element be attached to the frame in order to close the opening in the wire periphery. The present invention does not form a helix and does not include eyelets. In addition, in the present invention the single coiled wire is sufficient to be shaped to occlude defect openings such that no additional membrane element is necessary to build an occluding device. The device of Shaw et al. can not be used as

an occluding device without the membrane element. Thus, Shaw et al. does not disclose an occluding device made of a single wire.

Since the device of Shaw et al. differs from the device of Amplatz et al. there is no hint how to combine these ideas of making occluding devices. Especially, as just mentioned above, Amplatz et al. demands clamps at the ends of the device to collect together the number of wire strands.

Dependent claims 60-62 have been rejected under 35 U.S.C. § 103(a) as being anticipated by Amplatz et al. in view of newly cited Hyodoh et al. and Shaw et al. and further in view of Gainor et al. (US 2002/0169475). The deficiencies of Amplatz et al., Hyodoh et al. and Shaw are discussed above.

Gainor et al. appears to be directed at a septal defect closure device having 2 wire frames, each with a fabric membrane, wherein in the present invention the single coiled wire is sufficient to be shaped to occlude defect openings. Without providing the two membranes in addition to the wire frames no occluding effect is possible with the device according to Gainor et al.

Claims 60-62 depend indirectly from amended claim 40 and are believed to be similarly distinguished.

Dependent claims 67-69 and 71-73 have been rejected under 35 U.S.C. § 103(a) as being anticipated by Amplatz et al. (US 5,944,738) in view of Shaw et al. (US 6,171,329). Amplatz et al. does not teach a positioning system. Shaw et al. does teach a positioning system but does not teach or suggest a support structure that “comprises a single intertwined, intercoiled wire-like element having two ends and configured into a tissue and/or scrim and/or net structure”. Further, the positioning system differs from the positioning system according to the present invention. No retaining wire and guide wire are moved relative to an advancing element of Amplatz et al. or Shaw et al. Further, neither Amplatz et al. nor Shaw et al. disclose any auxiliary structure for aiding the deployment of the implantable device.

Claims 67-69 and 71-73 depend directly or indirectly from amended claim 40 and are believed to be similarly distinguished.

Having dealt with all the objections raised by the Examiner, it is respectfully submitted that the present application, as amended, is in condition for allowance. Thus, early allowance is earnestly solicited.

If the Examiner desires personal contact for further disposition of this case, the Examiner is invited to call the undersigned Attorney at 603.668.6560.

In the event there are any fees due, please charge them to our Deposit Account No. 50-2121.

Respectfully submitted,

By: /Steven J. Grossman/  
Steven J. Grossman, Ph.D.  
Reg. No. 35,001